E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0446; FRL-10195-01-OCSPP]

Pydiflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pydiflumetofen in or on caneberry subgroup 13-07A. The Interregional Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0446, is available online at *https://www.regulations.gov* or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency,

1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0446 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0446, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of September 22, 2021 (86 FR 52624) (FRL-8792-03-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8919) by the Interregional Research Project Number 4 (IR-4), Project Headquarters, North Carolina University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.699 be amended to establish a tolerance for residues of the fungicide pydiflumetofen, (3-(difluoromethyl)-*N*-methoxy-1-methyl-*N*-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1*H*-pyrazole-4-carboxamide) in or on caneberry subgroup 13-07A at 4 parts per million (ppm) and to revise the tolerance for

vegetable, fruiting, group 8-10 from 0.60 ppm to 0.8 ppm. That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the Notice of Filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing the tolerance for caneberry subgroup 13-07A at a different level than petitioned-for and is not increasing the tolerance for vegetable, fruiting, group 8-10 to 0.8 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result in infants and children from aggregate exposure to the pesticide chemical residue…."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pydiflumetofen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pydiflumetofen follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for pydiflumetofen, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pydiflumetofen and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of pydiflumetofen, see Unit III.A. of the August 12, 2019, rulemaking (84 FR 39761) (FRL-9997-09).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for pydiflumetofen used for human health risk assessment, see Unit III.B. of the May 24, 2018, rulemaking (83 FR 24036) (FRL-9976-66).

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C of the August 12, 2019, rulemaking.

Dietary exposure from food and feed uses. EPA's dietary exposure assessments have been updated to include the additional exposure from the new use on caneberry subgroup 13-07A. The chronic and acute dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity

Intake Database (DEEM-FCID) Version 4.02, which uses the 2005-2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As with the 2019 assessments, the chronic and acute dietary risk assessments were unrefined, assuming tolerance-level residues, 100% crop treated (100 PCT) for all commodities, and default processing factors.

Dietary exposure from drinking water. The new use on caneberry subgroup 13-07A does not result in an increase in the estimated residue levels in drinking water, so EPA used the same estimated drinking water concentrations identified in Unit III.C. of the August 12, 2019, rulemaking.

From non-dietary exposure. Since there are no new residential uses proposed under this petition, the prior residential assessment is unchanged, and no risks of concern were identified. The summary can be found in Unit III.C. of the August 12, 2019, rulemaking.

Cumulative effects from substances with a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pydiflumetofen and any other substances and pydiflumetofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pydiflumetofen has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor to 1X. See Unit III.D. of the August 12, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risk and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-intermediate-, and chronic term risks are evaluated by comparing the estimated aggregate food,

water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate MOE exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 9.1% of the aPAD for children 3 to 5 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 30% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate.

The short-term aggregate exposure assessment includes dietary (food and drinking water) and post-application dermal exposure. The dermal routes of exposure used in the aggregate exposure assessment were activities in gardens for adults and children 6 to less than 11 years old and golfing for youths 11 to less than 16 years old. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 350 for adults, 560 for children 6 to less than 11 years old, and 2,400 for youth 11 to less than 16 years old. Because EPA's level of concern for pydiflumetofen is an MOE of 100 or below, these MOEs are not of concern. No intermediate-term aggregate exposure scenarios were identified. Acute and chronic aggregate risks are equivalent to the dietary (food and drinking water) risks for those respective assessments and are not of concern.

Pydiflumetofen is classified as "Not Likely to be Carcinogenic to Humans" at doses that do not induce a proliferative response in the liver. The chronic reference dose will be protective of all chronic toxicity, including carcinogenicity, and is not of concern.

Determination of safety. Therefore, based on the risk assessments and information described above, EPA concludes that there is reasonable certainty that no harm will result in the general population, or to infants and children, from aggregate exposure to pydiflumetofen

residues. More detailed information can be found at *https://www.regulations.gov* in the document titled "Pydiflumetofen. Human Health Risk Assessment for Proposed New Foliar Use on Caneberry Subgroup 13-07A and Greenhouse Foliar/Drench Uses on Peppers and Greenhouse Foliar Uses on Head/Leaf Lettuce. Proposed New Soil Application Use on Cucurbit Vegetables, Crop Group 9; Amended/Increased Foliar Use Rate on Peanut; New Seed Treatment Uses on Edible-Podded Legume Vegetables Crop Subgroup 6A and Succulent Shelled Pea/Bean Crop Subgroup 6B; and Amended/Increased Seed Treatment Use Rate on Soybean." in docket ID number EPA-HQ-OPP-2021-0446.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the August 12, 2019, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex has not established a MRL for residues of pydiflumetofen in/on caneberry subgroup 13-07A. Codex has established MRLs for residues of pydiflumetofen at 0.5 ppm in/on eggplant, ground cherry, pepino, pepper (bell and non-bell), tomatillo, and tomato, and at 0.02 ppm in/on martynia, okra, and roselle. It is not possible to harmonize the U.S. tolerance for vegetable, fruiting, group 8-10 (0.60 ppm) with these Codex MRLs because decreasing the domestic tolerance could put U.S. growers at risk of violative residue levels despite legal use of pydiflumetofen according to the label. The already established U.S. tolerance is harmonized with

the Canadian MRLs for residues of pydiflumetofen in/on the individual crops of vegetable, fruiting, group 8-10.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance for Caneberry subgroup 13-07A at 5 ppm. IR-4 proposed a tolerance of 4 ppm based on combining the residue data for the representative commodities (blackberry and raspberry) in the Organisation for Economic Cooperation and Development (OECD) calculator analysis. EPA's practice is to conduct the OECD calculator analysis separately for each representative commodity. For pydiflumetofen, the OECD calculator analysis results in a tolerance of 5 ppm for Caneberry subgroup 13-07A.

IR-4 also requested an increase in the existing crop group tolerance for vegetable, fruiting, group 8-10 from 0.60 ppm to 0.8 ppm, based on its calculations entering the four new residue data points from the greenhouse bell and non-bell pepper field trials into the OECD MRL calculator. EPA's practice is to conduct the OECD calculator analysis separately for each representative commodity of a crop group. This was not possible because bell pepper and non-bell pepper each have two residue data points and the OECD MRL calculator requires a minimum of three data points. After considering an alternative approach of estimating an appropriate tolerance as well as the maximum residue in the submitted greenhouse field trial data, which was 0.480 ppm, EPA determined that residues in or on peppers from the proposed new greenhouse uses on peppers are expected to be covered by the currently established tolerance of 0.60 ppm. This was a minor use joint review with Canada's Pest Management Regulatory Agency (PMRA); PMRA came to the same conclusion and is maintaining its MRL for residues of pydiflumetofen in or on vegetable, fruiting, group 8-10 at 0.60 ppm.

V. Conclusion

Therefore, a tolerance is established for residues of pydiflumetofen, (3-(difluoromethyl)-*N*-methoxy-1-methyl-*N*-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1*H*-pyrazole-4-carboxamide) in or on caneberry subgroup 13-07A at 5 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 24, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMIAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.699, amend paragraph (a) by designating the table as table 1 and adding in alphabetical order in newly designated table 1 to paragraph (a) the entry "Caneberry subgroup 13-07A" to read as follows:

§ 180.699 Pydiflumetofen; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Caneberry subgroup 13-07A	5
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[FR Doc. 2023-03210 Filed: 2/14/2023 8:45 am; Publication Date: 2/15/2023]